K112348

JAN 19 2012

510(k) Summary of Safety and Effectiveness (21 CFR 807.92)

Date prepared: September 28, 2011

Submitter:
RS Medical
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Contact Person:
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Proprietary name:
RS-4i Plus Sequential Stimulator

Common name:
Powered Muscle Stimulator

Classified name:
Powered muscle stimulator for rehabilitation
CFR 890.5850 Product code: IPF, LIH

Intended use:
Interferential stimulation indications
- Relieve acute pain
- Relieve and manage chronic pain

Muscle stimulation indications
- Relax muscle spasms
- Prevent or retard disuse atrophy
- Maintain or increase range of motion
- Increase local blood circulation
- Re-educate muscle
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Substantial equivalence:
The RS-4i Plus is substantially equivalent to the RS-4i Muscle Stimulator Family (K032652). Both devices have the same intended use/indications for use and the same fundamental scientific technology.

Description of device:
The RS-4i Plus is 4 channel electrical stimulator that incorporate traditional muscle stimulation and interferential current stimulation modalities into a single unit. It has the

capability to program the device's output by the care giver to match the patient's condition through the use of pre-set selections. The RS-4i Plus is hand held with an electronic display, digital single processor, software/firmware controlled functions, user keypad, cable leads and electrode pads, multiple output channels, removable, rechargeable battery, and patient data files and retrieval capability.

Technological characteristics:

Several technological characteristics of the device were modified from the predicate. These include physical characteristics to enhance the usability of the device such as more information on display and additional function keys. The processor was changed from a DSP to a MCU component. The battery was changed from a NiMH type with charger to a removable Lithium-Ion smart battery type with charging dock. Patient leads were changed from 4 pairs that are bundled to 4 individual cables with 2 leads each. For patient data, both devices include a NVRAM adapter and the RS-4i Plus also includes a USB adapter.

The RS-4i Plus was assessed and tested for its basic unit characteristics and output specifications. The results show that the RS-4i Plus is equivalent to the RS-4i.

In support of the modifications in the RS-4i Plus, the device was tested and shown to conform to the following standards:

- ANSI/AAMI ES60601-1:2005 – Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- ANSI/AAMI ES60601-1:2005/C1:2009 – Medical electrical equipment Part 1: General requirements for basic safety and essential performance, Amendment 1
- IEC 60601-1-2 Edition 3:2007-03 – Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- ANSI/AAMI/IEC 62304:2006 – Medical device software, Software life cycle processes
- CEI IEC 601-2-10; 1987 – Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
- IEC 60601-2-10 Amendment 1 Edition 1.0 en:2001 – Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
- IEC 60601-2-10 Amendment 1 Corrigendum 1 – Technical Corrigendum: Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
- IEC 60601-1-11 Edition 1.0 2010-04 – Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60529 Edition 2.1 Consol. With Amendment 1:2001 – Degrees of protection provided by enclosures (IP code)
- IEC 60601-1-8 Ed. 2.0 2006-10 – General Requirements for Tests and Guidance for Alarm Systems used in Medical Devices
- ASTM E171 – Standard Specification for Standard Atmospheres for Conditioning and Testing Flexible Barrier Materials
- ASTM D4332 – Standard Practice for Conditioning Containers, Packages, Packing

- ASTM D5276 – Standard Test Method for Drop Test of Loaded Conatiners
- ASTM D4728 – Standard Test Method for Random Vibration Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K112348
Trade/Device Name: RS-4i Plus Sequential Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF, LIH
Dated: December 22, 2011
Received: December 23, 2011

Dear Mr. Cougill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112348

Device Name: RS-4i Plus Sequential Stimulator

Indications For Use:

Interferential Stimulation Indications:

- Relieve acute pain
- Relieve and manage chronic pain

Muscle Stimulation Indications:

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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